

REMARKS

Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38 and 40-47 are in the case and presented for reconsideration.

Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38 and 40-47 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/173,339. Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38 and 40-47 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 of copending Application No. 10/173,197. Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38 and 40-47 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/173,298. Duly executed Terminal Disclaimers are enclosed herewith. Accordingly, these rejections should be removed.

Claims 1, 3, 4, 6, 8-11, 13, 14, 16-23, 25, 27, 28, 30, 32-38, and 40-47 have been have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,868,673 (Vesely) in view of U.S. Patent No. 5,353,354 (Keller et al.) and further in view of U.S. Patent No. 6,347,241 (Burbank et al.).

Applicant respectfully traverses as follows. The invention being claimed in Claims 1, 4, 8 and 16 respectively of the present application is an apparatus for determining the position of an object within a patient's body comprising at least one acoustic generator for generating a first acoustic wave toward the body at a first frequency and a wireless acoustic tag fixed to the object comprising a shell having a cavity and a medium contained within the shell wherein the wireless tag emits a second acoustic wave at a second frequency different from the first frequency (Claim 1) or at least one acoustic generator for generating a first acoustic wave toward the body at a first frequency and a wireless acoustic tag fixed to the object that emits a second acoustic wave at a second frequency different from the first frequency (Claim 4) or at least one acoustic generator for generating acoustic waves toward the body and a wireless transducer that emits electromagnetic radiation responsive to the acoustic wave (Claim 8) or at least one field

generator for generating an electromagnetic field within the body and a wireless transducer fixed to the object that emits acoustic waves responsive to the electromagnetic field (Claim 16); and one or more detectors to detect the second acoustic wave (Claim 1) or to detect the reflected acoustic waves (Claim 4) or to detect the emitted electromagnetic radiation (Claim 8) or to detect emitted acoustic waves (Claim 16) and to generate signals responsive thereto; and a signal processor for processing the signals to determine six-dimensional position and orientation coordinates of the object within the patient's body.

The invention being claimed in Claims 25, 28, 32 and 40 respectively of the present application is method for determining the position of an object within a patient's body comprising the steps of fixing a wireless acoustic tag to the object wherein the tag comprises a shell having a cavity and a medium contained within the shell wherein the wireless tag emits a second acoustic wave in response to a first acoustic wave at a first frequency wherein the second acoustic wave is at a second frequency different from the first frequency (Claim 25) or fixing a wireless acoustic tag to the object wherein the wireless tag emits acoustic waves in response to first acoustic waves at a first frequency with a first spatial pattern of intensity variation wherein the acoustic waves are emitted by the tag at a second frequency with a second special pattern of intensity variation (Claim 28) or fixing a wireless transducer to the object wherein the transducer emits electromagnetic radiation in response to acoustic waves directed toward the body (Claim 32) or fixing a transducer to the object wherein the transducer emits acoustic waves in response to a generated electromagnetic field (Claim 40); and inserting the object in the patient's body; and detecting the second acoustic wave (Claim 25) or detecting the reflected acoustic waves (Claim 28) or detecting the emitted electromagnetic radiation (Claim 32) or detecting the emitted acoustic waves (Claim 40); and to generate signals responsive thereto so as to determine six-dimensional position and orientation coordinates of the object within the patient's body.

Vesely discloses a system for carrying out surgery, biopsy and ablation of a tumor or other physical anomaly wherein its system uses transducers that are hard-wired from a tumor location in breast tissue all the way back to its computer system 1010 wherein the leads "can be taped to the patient's skin". Col. 7, lines 12-16. Vesely does not in any way teach or suggest a wireless acoustic tag fixed to the object comprising a shell having a cavity and a medium contained within the shell wherein the wireless tag emits a second acoustic wave at a

second frequency different from the first frequency (Claim 1) or at least one acoustic generator for generating a first acoustic wave toward the body at a first frequency and a wireless acoustic tag fixed to the object that emits a second acoustic wave at a second frequency different from the first frequency (Claim 4) or at least one acoustic generator for generating acoustic waves toward the body and a wireless transducer that emits electromagnetic radiation responsive to the acoustic wave (Claim 8) or at least one field generator for generating an electromagnetic field within the body and a wireless transducer fixed to the object that emits acoustic waves responsive to the electromagnetic field (Claim 16) in conjunction with a signal processor to determine six-dimensional position and orientation coordinates, such as six-dimensional position and orientation coordinates, i.e. X, Y and Z axis directions and yaw, pitch and roll orientations), such as found with Applicant's claimed present invention. Moreover, for the same reasons as outlined above, Vesely fails to teach or suggest these limitations as part of a method for determining the position of an object within a patient's body such as set forth in Applicant's Claims 25, 28, 32 and 40 of the Present Application.

Contrary to the Examiner's interpretation of the teachings of this reference, Vesely is clearly directed to a three-dimensional tracking system only and entirely incapable of determining both position and orientation coordinates (six dimensional position and orientation coordinates, i.e. X, Y and Z axis directions and yaw, pitch and roll orientations) such as found with Applicant's claimed present invention.

Particularly, in the portion of the teaching pointed out by the Examiner, i.e. Col. 4, Lines 55-65, Vesely specifically teaches:

Imaging modality system 1014 acquires 2-D, 3-D or 4-D image data sets from an imaging source, such as fluoroscopy, an MRI (magnetic resonance imaging), CT (computerized tomography) or 2-D or 3-D ultrasound device, to provide a "template" through or against which the shape, position and movement of instrument 1030 being tracked can be displayed. The template typically takes the form of an image of the environment surrounding the instrument (e.g., a bodily structure). It should be noted that if multiple (3-D) volumes are acquired at different time intervals, a 4-D image is obtained (i.e., 3-D image changing over time).

Thus, the system and method of Vesely is only capable of producing "multiple (3-D) volumes" and is required to be combined with a separate imaging modality in order to produce a 4-D image at best.

Keller et al. is directed to the acquisition and display of ultrasonic images from sequentially oriented image planes. It is important to note that these image planes are derived purely from an external ultrasonic scanhead 10 which is used on an exterior surface of the patient's body. See FIGS. 5 and 6.

Burbank actually teaches an ultrasonic and x-ray detectable biopsy site marker and apparatus for applying it that merely uses radio opaque gelatin pellets to mark a biopsy site in tissue. These gelatin or collagen-based pellets could not in any way cause signals that are generated and received by a signal processor for determining six-dimensional position and orientation coordinates, i.e. X, Y and Z axis directions and yaw, pitch and roll orientations of a wireless acoustic tag/wireless transducer as found with Applicant's claimed present invention. But rather, the Burbank et al. pellets are based strictly on hydration and are identified in the tissue of the patient's body based on the trapped air pockets in the gelatin or collagen (that are visible on an ultrasound image) that result from hydration of the implanted pellet. See Col. 4, Line 57 – Col. 5, Line 11.

The claimed present invention does not at all use or claim Burbank et al.'s hydration-based gelatin or collagen pellet. And, Burbank et al. clearly teaches away from the wireless tag/wireless transducer six-dimensional position and orientation coordinate technology in which the Applicant is claiming. Thus, at the time of Applicant's invention, the art actually taught away from the Applicants' invention. Thus, Burbank et al. taught away from the invention as claimed, and therefore, cannot rightly be combined with Vesely and Keller et al. to render the present invention obvious.

Therefore, one skilled in the art would not be lead by the teachings of Keller et al. to experiment with their external ultrasonic scanhead and ultrasonic image plane display system or Burbank et al.'s hydration-based gelatin or collagen pellet. Thus, contrary to the Examiner's assertions, Vesely is actually evidence of the non-obvious of the present invention. See *In re Hedges*, 783 F.2d 1038, 228 U.S.P.Q. 685, 687 (Fed. Cir. 1986).

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As taught in Col. 4, Lines 55-65 of Vesely, its system can only ensure that “multiple (3D) volumes are acquired at different time intervals, a 4-D image is obtained (i.e., 3-D image changing over time)”. Accordingly, this 3-D volume technique can never achieve the determination of six-dimensional position and orientation coordinates, i.e. X, Y and Z axis directions and yaw, pitch and roll orientations of a wireless acoustic tag or wireless transducer such as found with Applicant’s claimed present invention. Thus, one of ordinary skill in the surgical navigation field would be entirely discouraged from following the path set out in the teachings of Vesely. And, it is clear that this reference actually teaches away from Applicant’s claimed present invention.

Therefore, for the reasons outlined above, the Applicants claimed present invention is both patentably distinct and non-obvious over the cited prior art references, and favorable action is respectfully requested.

Respectfully submitted,

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